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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/813,323	03/10/1997	DAVID BALTIMORE	50659/JPW/JM	3314

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12/31/2002

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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 12/31/2002

31

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/813,323

Applicant(s)

BALTIMORE ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 93 and 94 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/02 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 3, 4 and 92 and adds new claims 93 and 94, which are related to claims 3, 4 and 92.

Accordingly, claims 93, 94 are being examined.

The following are the remaining rejections.

SEQUENCE RULE COMPLIANCE

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1)

and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821-25 for the following reasons:

The legends of figures 1, 2A-D, 5A-B and 6A-B referring to nucleotide sequences and/or amino acid sequences of CRAF1 are not accompanied with sequence identification numbers.

Further, in the specification, the amino acid sequence of residues 324-567 of CRAF1 on page 11 is not accompanied by a sequence identification number.

renew - **REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION**

Claims 93-94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claims 93-94 are indefinite, because it is not clear in claims 93-94 what the size of the consecutive amino acids is.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION, NEW REJECTION

The following is a quotation of the first paragraph of 35 USC 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93- 94 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

Claim 93 is drawn to an isolated protein consisting of consecutive amino acids, the sequence of which amino acid is set forth in SEQ ID NO:2, which protein has the amino acid proline corresponding to the proline at position 568 of SEQ ID NO:2 at its carboxy terminus and extends to the amino acid glycine corresponding to the glycine at position 416 of SEQ ID NO:2.

Claim 94 is drawn to an isolated protein comprising consecutive amino acids, the sequence of which amino acid is included within SEQ ID NO:1, which protein has the amino acid proline corresponding to the proline at position 567 of SEQ ID NO:1 at its

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carboxy terminus and extends to at least the amino acid glycine corresponding to the glycine at position 415 of SEQ ID NO:1.

remain Claim 93 encompasses a protein consisting of two or three consecutive amino acids as set forth in SEQ ID NO:2, wherein said protein comprises proline corresponding to proline at position 568 of SEQ ID NO:2 and extends to glycine corresponding to glycine at position 416 of SEQ ID NO:2, and wherein said protein has any structure and any length provided it has some consecutive amino acids of SEQ ID NO:2, and has proline and glycine.

Claim 94 encompasses a protein comprising a fragment of SEQ ID NO:1, comprising proline corresponding to proline at position 567 of SEQ ID NO:1 and extends at least to glycine corresponding to glycine at position 415 of SEQ ID NO:1, wherein said protein has any structure and any length provided it comprises a fragment of any length of SEQ ID NO:1, and has proline and glycine.

Although drawn specifically to the DNA art, the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly relevant to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise

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definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

The instant specification however fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus of proteins. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed. In addition, no common functional attributes that identify the claimed genus of proteins are disclosed, because the function of a protein could be abolished, even with substitution of only one amino acid of the protein (Burgess et al. Journal of Cell Biology, 1990, 11: 2129-2138).

The general knowledge and level of skill in the art do not supplement the omitted description, because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the claimed genus of proteins, SEQ ID NO:1 or 2 alone is insufficient to describe the claimed genus of proteins. One of skill in the art would reasonably

conclude that the disclosure fails to provide a representative number of the claimed genus of proteins. Thus, applicant was not in possession of the claimed genus of proteins.

Thus, there is insufficient support of claims 93-94 as provided by the Interim Written Description Guidelines published in the June 5, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645. Therefore, only an isolated polypeptide comprising SEQ ID NO: 1 or 2, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph.

REJECTION UNDER 35 USC 102

New claims 93 and 94 are rejected under 35 USC 102(b) pertaining to anticipation by Sato et al remains for reasons already of record in paper No.26.

Claim 93 is drawn to an isolated protein consisting of consecutive amino acids, the sequence of which amino acid is set forth in SEQ ID NO:2, which protein has the amino acid proline corresponding to the proline at position 568 of SEQ ID NO:2 at its carboxy terminus and extends to the amino acid glycine corresponding to the glycine at position 416 of SEQ ID NO:2.

Claim 94 is drawn to an isolated protein comprising consecutive amino acids, the sequence of which amino acid is included within SEQ ID NO:1, which protein has the amino acid proline corresponding to the proline at position 567 of SEQ ID NO:1 at its carboxy terminus and extends to at least the amino acid glycine corresponding to the glycine at position 415 of SEQ ID NO:1.

Applicant argues that the claimed human peptide in claim 93 is shorter than the human peptide taught by Sato et al.

Applicant further argues that that SEQ ID NO:1 is a peptide derived from a mouse, whereas Sato et al discloses two human derived peptides, one of 543 amino acids (full length CRAF-1) and the other of 181 amino acid (a fragment of CRAF1). Applicant asserts that the specific peptides described in claim 94 contain residue differences with both the fragment and the full length human sequences disclosed by Sato et al. Applicant asserts that there is a threonine residue at position 390 in the claimed peptide, whereas both the Sato peptides have a methionine at their corresponding position (residue 366 by Sato numbering). Applicant asserts that there is a further difference at residue 373, with the claimed peptide having an alanine at that position and both the Sato fragments having a valine (residue 349 by Sato's numbering). Applicant concludes that thus Sato et al do not anticipate the claimed invention.

Applicant's arguments set forth in paper No.27 have been considered but are not deemed to be persuasive for the following reasons:

Claim 93 encompasses a protein consisting of two or three consecutive amino acids as set forth in SEQ ID NO:2, wherein said protein comprises proline corresponding to proline at position 568 of SEQ ID NO:2 and extends to glycine corresponding to glycine at position 416 of SEQ ID NO:2, and wherein said protein has any structure and any length provided it has some consecutive amino acids of SEQ ID NO:2, and has proline and glycine.

Claim 94 encompasses a protein comprising a fragment of SEQ ID NO:1, comprising proline corresponding to proline at position 567 of SEQ ID NO:1 and extends at least to glycine corresponding to glycine at position 415 of SEQ ID NO:1, wherein said protein has any structure and any length provided it comprises a fragment of any length of SEQ ID NO:1, and has proline and glycine.

The sequence taught by Sato et al has some consecutive amino acids of SEQ ID NO: 1 and 2, and has proline and glycine, and thus seems to be the same as the claimed sequences, and meets all the limitation of the claims.

Concerning claim 93, the length of the sequence is not recited in the claim, and thus Applicant's argues limitation not in the claim.

Concerning claim 94, the claimed protein does not recite threonine at position 390, and alanine at position 373, which are outside of the positions 415 to 567 of SEQ ID NO:1. Thus Applicant's argues limitation not in the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

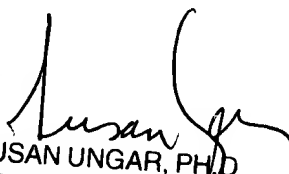
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

December 20, 2002


SUSAN UNGAR, PH.D
PRIMARY EXAMINER